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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,595	07/05/2000	Leena Peltonen	VOSS1130	1041

7590 09/27/2002

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	16

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,595	PELTONEN ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 4 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 are cancelled and claims 29-61 are added* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary amendment filed 24 November 2000 prior to patent examination as to cancellation of Claims 1-28 and addition of new Claims 29-61, a preliminary amendment filed 19 April 2002 and applicant's petition for extension of time of five months have been entered. Thus, Claims 29-61 are pending and the following is applicable to the pending claims.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 29-48 and 54, drawn to a polynucleotide, vector and a cell for the polynucleotide directed biosynthesis of the polypeptide and a pharmaceutical composition comprising the polynucleotide, are classified in class 536, subclass 23.1, class 435, subclass 320.1 and 69.1, class 514, subclass 44.

II. Claims 49-51, 57 and 58, drawn to a polypeptide or a polypeptide derivative and a pharmaceutical composition comprising the polypeptide, are classified in class 530, subclass 350^{+}, and class 514, subclass 2.

III. Claims 52-53 and 59-60, drawn to an antibody and a pharmaceutical composition comprising the antibody, are classified in class 530, subclass 387.1, class 424, subclass 130.1^{+} and 141.1.

IV. Claim 55, drawn to a method of testing for autoimmune polyendocrinophathy candidiasis ectodermal dystrophy (APECED) via investigating mutation in polynucleotide molecule, is classified in class 536, subclass 23.1, class 424, subclass 9.1, class 435, subclass 6 and 440, and class 514, subclass 44.

V. Claim 61, drawn to a method of treating a patient having APECED comprising contacting a cell of the patient with a polynucleotide molecule, are classified in class 536, subclass 23.1, class 424, subclass 9.1, class 435, subclass 7.1, and class 514, subclass 44.

VI. Claim 56, drawn to a method of testing for autoimmune polyendocrinophathy candidiasis ectodermal dystrophy (APECED) via investigating a mutated polypeptide molecule, is classified in class 530, subclass 350, 387.1 and 388.1, class 435, subclass 7.1, class 424, subclass 9.1 and 130.1^{+}, and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention II is drawn to polypeptide and Invention III to an antibody while Invention I is drawn to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is bale to directing biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention III is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention I (polynucleotide) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide, while Invention III is drawn to immunoglobulin, a polypeptide. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The nucleic acid is composed of deoxyribonucleotides linked by phosphodiester bonds and forms a double helix as a stable conformation that is a functionally structural characteristic. While antibody is composed of amino acid residues linked by peptide bond. Thus, biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions II (polypeptide) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-

shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Invention I is related to Inventions IV and V as product and alternative processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups IV and V demonstrate alternative methods of use.

Invention I and Invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the mechanism of immobilized polynucleotide on DNA microarray chip for genomic typing analysis differs from action of mutant polypeptide occurring in a patient which is subject to being analyzed in order to identifying a disease state.

Inventions IV, V and VI are related as different and/or distinct methods, a method producing a polypeptide, a method of testing for autoimmune polyendocrinophathy candidiasis ectodermal dystrophy (APECED) via investigating mutation in polynucleotide molecule and treating a patient having APECED comprising contacting a cell of the patient with a polynucleotide molecule, a method of testing for APECED via investigating a mutated polypeptide molecule, respectively. These two methods differ with respect to method steps, end-products, targets, ingredients; therefore, each method is patentably distinct.

Invention II is related to Inventions VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in proteinchip array to investigating signal transduction pathway, for example.

Invention II is unrelated to Inventions IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide is not a target for identifying a disease state in Claims 55 and 61 of Group IV which instead analyzes a mutation occurring in the polynucleotide in a patient carrying the said disease; i.e. the mode of operation is different thereof.

Invention III is unrelated to Inventions IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, molecular mechanism of the antibody recognizes a polypeptide is distinct from mode of action of an antibody against a polynucleotide.

Invention III and Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody can be immobilized on a gold chip of surface plasma resonance for studying a real time protein-protein interaction, for example.

Additional Election Under 35 USC 121

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed polynucleotide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required under 35 US 121 (1) to elect a host for production of polypeptide molecule from Claim 47 of Group I since of the host as set forth in Claim 47 are differently classified and searched. For example, isolated cells and preparation thereof are classified in class 435, subclass 252.3 and 325 whereas transgenic animal are classified in class 800, subclass 295. Note that the cells per se are not an animal nor a plant and an animal per se is not a plant. None of the three can be substituted one for other.

In the above, the response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL
September 17, 2002

Christopher S. F. Low

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